## JUN 2 5 2001

## 21.0 510(K) SUMMARY

K010957

Submitter:

Jeneric/Pentron, Inc.

Address:

53 North Plains Industrial Road Wallingford, Connecticut 06492

Contact Tel: 203-265-7397 X619

Contact Fax: 203-265-7662

Contact Person: Annmarie Tenero

Date Summary Prepared: June 20, 2001

Quell Desensitizer is a two-step process applied by a dentist to help minimize the sensitivity of a patients tooth. We believe that Quell Desensitizer is substantially equivalent to D/Sense II, K992629, by Centrix, Inc. Both Quell Desensitizer and D/Sense II are tooth desensitizers, which help desensitize a patients tooth. Quell Desensitizer contains fewer ingredients than D/Sense II which does not affect safety or effectiveness. Quell Desensitizer can be used under crowns and bridges and on cervical lesions.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

## JUN 2 5 2001

Ms. Annmarie Tenero Jeneric/Pentron, Incorporated 53 North Plains Industrial Road P.O. Box 724 Wallington, Connecticut 06492-0724

Re: K010957

Trade/Device Name: Quell Desensitizer

Regulation Number: 872.3260

Regulatory Class: II Product Code: LBH Dated: March 29, 2001 Received: March 30, 2001

Dear Ms. Tenero:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the <u>Code of Federal Regulations</u>, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address

"http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yo

Timoth A. Ulatowski

Director

Division of Dental, Infection Control and General Hospital Devices Office of Device Evaluation Center for Devices and Radiological Health

## 5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): 🕇 🔾	10957
DEVICE NAME: QUELL DESENSIT	
INDICATION FOR USE: Quell Desensitize minimize the sensitivity of a patients tooth.	zer is a two-step process applied by a dentist to help
Also, Quell Desensitizer can be used on cerv bridges where conventional cementation (zir	vical lesions, under amalgams or crowns and no phosphate or glass ionomer) is used.
Quell Desensitizer can be used immediately sensitivity.	before temporization, to prevent post-operative
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(PLEASE DO NOT WRITE BELOW TI IF NEEDED.)	HIS LINE – CONTINUE ON ANOTHER PAGE
Concurrence of CDRH, Offi	ce of Device Evaluation (ODE)
Prescription Use VOR	Over -The-Counter-Use
Prescription Use V OR (Per 21 CFR 801.109)	(Optional Format 1-2-96) 5.0
	(Division Sign-Off)
Jeneric/Pentron, Iuc. 510K Submission — QUELL DESENSITIZER	Division of Dental, Infection Control,
	310(k) Number 655 4 K0/095